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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,660	09/27/2001	Joachim Buenger	MERCK 2305	9098

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EXAMINER	
KISHORE, GOLLAMUDI S	
ART UNIT	**PAPER NUMBER**
1615	12

DATE MAILED: 11/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/936,660	Buenger
Examiner	**Art Unit**
Gollamudi Kishore, Ph.D	1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Sep 4, 2003* .

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-11 and 16* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-11 and 16* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *11*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The amendment filed on 9-4-03 is acknowledged.

Claims included in the prosecution are 1-11 and 16.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-11 and 16 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, as set forth in the previous action.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that the present specification on page 6, lines 28-34 cites five published German patent applications and therefore, one skilled in the art would be able to use a micromixer without undue experimentation. These arguments are not found to be persuasive since instant invention deals with the preparation of cosmetic formulations *immediately before use.* According to the specification and the canceled claims 14 and 15, the final preparation is in the form of a gel or a cream. Who prepares the final form of the cosmetic preparation which is in the form of a gel or a cream? The customer? Or does the micromixer itself forms the final product? Is the micromixer

attached to other units containing the individual components which are responsible for the final product form? Instant specification does not adequately describe as to how to use and make the final products using the micromixers; thus, one of ordinary skill in the art will not be able to practice the invention without undue experimentation. The rejection is maintained.

3. Claims 1-11 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear as to what applicant intends to convey by 'micromixer' in claim 1. Generally the pharmaceutical preparations and cosmetic preparations are used in macro scale and the term 'micro' (in the term 'micromixer') is used to denote minute amounts (that is micro scale). There is no adequate description of the term in the specification. Applicant cites some references in the specification which are not in English and one cannot determine what the term represents. An adequate description of this is essential since one would expect the function of a micromixer is to mix the components to a homogeneous preparation; however, according to the dependent claim 3, the preparation is stirred after using the micromixer.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that the breadth of a claim is not to be equated with

indefiniteness. This argument is not found to be persuasive since the rejection is made based on the lack of clarity. As pointed out above, cosmetic preparations are prepared on a macro scale and instant specification does not disclose the connection between the so called micromixer and the final preparations (which are gels and creams according to the specification) which are on the macro scale.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by DE 195 11 603 of record (English equivalent: US 5,904,424) or DE 196 11 270 also of record.

DE 603 and DE 270 both disclose a micromixer and a process of mixing small quantities of two liquids (note English abstract (in US 424) for DE 603 and the abstract, Figures and claims for DE 270) . Though the preamble states 'for the preparation of cosmetic or pharmaceutical formulations, instant clams do not define what the liquids are and therefore, the prior art process meets the requirements of instant claims.

(e) the invention was described in-
(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

6. Claims 1-3 are rejected under 35 U.S.C. 102(b) or 102 (e) as being anticipated by DE 197 46 585 or DE 197 46 583 (English equivalent, US 6,457,854) or DE 197 46 584 (English equivalent US 6,367,964) all are of record.

DE 585, 583 and 584 disclose a micromixer and a process of mixing small quantities of two liquids (note the abstract and claims of DE 585; English abstracts, Figures and claims for 583 and 584). As pointed out above, though the preamble states 'for the preparation of cosmetic or pharmaceutical formulations, instant clams do not define what the liquids are and therefore, the prior art process meets the requirements of instant claims.

Note: the 102 (b) rejections will be reconsidered, upon the submission of English translations of the priority documents.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at

the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1-11 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB 2,145,107 by itself, in view of either DE 195 11 603 (English equivalent: US 5,904,424) or DE 196 11 270, DE 197 46 585 or DE 197 46 583 (English equivalent, US 6,457,854) or DE 197 46 584 (English equivalent US 6,367,964) cited above.

As pointed out before, GB discloses a process of preparation of liposomes and emulsions. The process involves mixing the two components before use. The components are fed into the mixing chamber with turbulent mixing in the mixing chamber (note abstract, page 1, lines 50-55, page 3, line 46 through page 4, line 61, page 5, lines 10-41). Emulsions are disclosed on page. Lines 19-20). Although GB does not explicitly disclose that the micromixer is temperature controlled, since it is a sealed unit, it is deemed that it meets the requirements of instant claims. GB does not teach that one of the components is an oil. However, it is art known that emulsions can only be formed when an oily phase is combined with the aqueous phase. Therefore, it is deemed obvious to one of ordinary skill in the art to use an oil, either synthetic or natural, if the desired goal is to prepare an emulsion. GB does not appear to teach tubings from each chamber leading to the mixing chamber. However, in view of the presence of tubings in dispensers to draw out the liquid at the bottom, it is deemed obvious to manipulate the basic teachings of GB with the expectation of obtaining almost entire quantity of the dispensable material from the chambers. The criticality of

warming the components is unclear to the examiner since it would be obvious to one skilled in the art that oils solidify depending upon the room temperature and a solidified oil cannot be dispensed.

What is lacking in GB is an explicit teachings that the mixer is a micromixer.

The DE references as pointed out above, each teach micromixers for preparing homogeneous mixtures of two liquids. DE 603 (US 5,904,424) in addition teaches that one can homogenize even very small quantities of liquids with high efficiency and is simple to manufacture (col. 1, lines 44-46 of US 424). DE 583 (US 6,457,854) in addition teaches that since heat transfer conditions in the micromixer in all the passage sections are entirely uniform, completely uniform temperature control can be established in all the sections of the passages in the micromixer simply by regulating the temperature of the housing parts. According to 854, this contributes to increasing the operating reliability and enables exact temperature control (col. 1, line 64 through col. 2, line 9). DE 584 (US 6,367,964) in addition teaches that the time and work involved in using the micromixer are less (columns 1-2).

Even assuming that GB does not teach the use of micromixers, such a use would have been obvious to one of ordinary skill in the art since the DE references each teach the availability of such mixtures and the advantages of using such mixers.

The examiner cites the reference of Ford (US 4,776,500) to show the knowledge in the art of using tubings from the containers.

Applicant's arguments with regard to GB have been fully considered, but are not found to be persuasive. Applicant argues that GB does not teach a micromixer. This argument is not found to be persuasive since there is no specific definition for 'micromixer' in the specification. Even the DE documents cited in the specification does not provide a specific definition for the term. Applicant's arguments that there is no teaching or suggestion that the mixing chamber has communicating channels to allow multiple mixing conditions, the examiner points out that instant claim does not require multiple communicating channels and the reference teaches on page 2, line 28 teaches 'feed means'; since in the reference there are two liquids coming into the mixing chamber through two channels, they are construed as the communicating channels. Furthermore, instant specification does not provide a specific definition for the term.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ***G.S. Kishore*** whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [**thurman.page@uspto.gov**].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published

in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.

Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

November 10, 2003